1.0 PURPOSE

The purpose of this policy is to identify requirements for data management and statistics for Division of AIDS (DAIDS) funded and/or sponsored clinical trials.

2.0 SCOPE

This policy applies to all clinical trials funded and/or sponsored by DAIDS outside of the HIV/AIDS Clinical Trials Networks.

3.0 BACKGROUND

It is important that clinical research funded and/or sponsored by DAIDS is of the highest quality and fulfills our goals of collecting complete and accurate trial data and of ensuring the safety of study participants. Clinical trial data needs to be managed in such a way as to ensure the authenticity and integrity of the data elements collected and to comply with applicable regulations and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines.

It is also important for an appropriately qualified and experienced statistician to participate in the development and conduct of the clinical trial. The statistician needs to ensure that statistical principles are appropriately applied during the design, conduct, and analysis phases of the clinical trial.

4.0 DEFINITIONS

Clinical trial – a prospective study of human subjects designed to answer questions about biomedical or behavioral interventions, e.g., drugs, treatments, devices, or new ways of using known treatments to determine whether they are safe and effective.

DAIDS sponsored – DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to Food and Drug Administration (FDA) and initiation of the study) and oversight for the trial.

DAIDS funded – DAIDS is providing financial support for trial or study.

Data Collection Site – The location where clinical trial data is collected and case report forms are completed (usually the trial site).

Data Management Facility – The organization responsible for managing the database and handling and processing the data gathered during a clinical trial.

Note: For additional definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

Principal Investigator (PI) – The PI or designee is responsible for:

- Utilizing an appropriate clinical data management facility to manage the data elements collected;
- Collaborating with an appropriately qualified and experienced statistician to participate in the development, conduct, and analysis of the clinical trial; and
- Developing a plan to provide objective evidence of compliance with the defined clinical data management and statistical requirements.

DAIDS Program/Project Officer – The DAIDS Program/Project Officer is responsible for ensuring and documenting that the defined clinical data management and statistical requirements are met.

Office for Policy and Clinical Research Operations (OPCRO) – OPCRO is responsible for:

- Reviewing and approving the clinical data management and statistical documentation generated in compliance with the data management and statistics requirements.
- Determining the suitability of using newly established data management facilities (as applicable) and documenting the approval/non-approval decision made.

6.0 POLICY

Data Management

The clinical trial data management system located at the data collection site(s) must comply with the requirements listed in Appendix 1, Data Management Requirements for Data Collection Sites.

The clinical trial data management system located at the data management facility must comply with the requirements listed in Appendix 2, Data Management Requirements for Data Management Facilities.

It is the preference of DAIDS that experienced clinical data management facilities are utilized for all clinical trial data management activities. However, use of a newly established data management facility will be considered on a case-by-case basis and will require approval obtained in advance from OPCRO.

Statistics

All clinical trials must have an appropriately qualified and experienced statistician and must comply with the requirements listed in Appendix 3, Statistical Requirements.

7.0 REFERENCES

Statistical Principles for Clinical Trials, International Conference on Harmonisation E9
http://www.ich.org/LOB/media/MEDIA485.pdf

Guidance for Industry – Computerized Systems Used in Clinical Trials, Draft Guidance, September 2004
http://www.fda.gov/cder/guidance/6032dft.htm

National Cancer Institute (NCI), Division of Cancer Prevention (DCP) Data Management Requirements
http://www3.cancer.gov/prevention/CTR/consortia/DataMgmtRqmts.doc

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

- Appendix 1 – Data Management Requirements for Data Collection Sites
- Appendix 2 – Data Management Requirements for Data Management Facilities
- Appendix 3 – Statistical Requirements

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006